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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/680,121	10/04/2000	Cynthia K. French	107-206-C	7802

34313 7590 02/24/2004

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EXAMINER	
NICKOL, GARY B	

ART UNIT	PAPER NUMBER
1642	

DATE MAILED: 02/24/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/680,121	FRENCH ET AL.	
	Examiner	Art Unit	
	Gary B. Nickol Ph.D.	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on 12-12-03.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 58-76 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claims 58-76 are pending.

(Please note: the Claims presented in the Amendment filed 08/26/03 have been renumbered according to Rule 1.126.)

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

1. Claim 58, drawn to a method for detecting a polynucleotide of SEQ ID NO:1 comprising contacting a sample using a polynucleotide probe or primer, classified in class 435, subclass 6.

2. Claim 59, drawn to a method of inhibiting the expression of SEQ ID NO:2 in a cell comprising employing an antisense sequence, classified in class 435, subclass 375.

3. Claims 60-62, drawn to a composition comprising monoclonal or polyclonal antibody that binds to SEQ ID NO:2, classified in class 530, subclass 387.1.

4. Claim 63, drawn to a method for detecting a polypeptide of SEQ ID NO:2 in a sample comprising contacting a sample with an antibody that specifically binds to said polypeptide, classified in class 435, subclass 7.1.

5. Claims 64-65 (in part), as specifically drawn to a method of diagnosing prostate cancer in a subject comprising detecting a diagnostic amount of the mRNA of SEQ ID NO:1, classified in class 424, subclass 9.1, class 436, subclass 6.

6. Claims 64-65 (in part), as specifically drawn to a method of diagnosing prostate cancer in a subject comprising detecting a diagnostic amount of the polypeptide of of SEQ ID NO:2, classified in class 424, subclass 9.1, class 435, subclass 7.23.

7. Claims 66-67, drawn to a method of detecting prostate cancer cells in subject comprising administering a compound comprising an antibody coupled to a label, classified in class 424, subclass 155.1.

8. Claim 68 (in part), as specifically drawn to a method for following the progress of prostate cancer in a subject comprising detecting first and second amounts of the mRNA of SEQ ID NO:1, classified in class 424, subclass 9.1, class 436, subclass 6.

9. Claim 68 (in part), as specifically drawn to a method for following the progress of prostate cancer in a subject comprising detecting first and second amounts of the polypeptide of SEQ ID NO:2, classified in class 424, subclass 9.1, class 435, subclass 7.23.

10. Claim 69 (in part), as specifically drawn to a method for the prophylactic or therapeutic treatment of prostate cancer in a subject comprising administering to the subject an antisense sequence, classified in class 435, subclass 375.

11. Claim 69 (in part), as specifically drawn to a method for the prophylactic or therapeutic treatment of prostate cancer in a subject comprising administering to the subject an inactive analog polypeptide of SEQ ID NO:2 that acts as a decoy, classified in class 424, subclass 184.1.

12. Claim 69 (in part), as specifically drawn to a method for the prophylactic or therapeutic treatment of prostate cancer in a subject comprising administering to the subject an inactive analog polypeptide of SEQ ID NO:1 that acts as a decoy, classified in class 424, subclass 184.1.

13. Claim 69 (in part), as specifically drawn to a method for the therapeutic treatment of prostate cancer in a subject comprising administering to the subject an immunotoxin that specifically binds to the polypeptide of SEQ ID NO:2 in an amount effective to inhibit metastasis of prostate cancer cells, whereby inhibition of metastasis provides the treatment of prostate cancer, classified in class 424, subclass 278.1.

14. Claim 69 (in part), as specifically drawn to a method for the therapeutic treatment of prostate cancer in a subject comprising administering to the subject an immunotoxin that specifically binds to the polypeptide of SEQ ID NO:1 in an amount effective to inhibit metastasis of prostate cancer cells, whereby inhibition of metastasis provides the treatment of prostate cancer, classified in class 424, subclass 278.1.

15. Claims 70-72 (in part), as specifically drawn to a method of eliciting in a subject an immune response against a cell bearing a polypeptide of SEQ ID NO:2 comprising administering a recombinant polynucleotide encoding an immunogenic polypeptide analog of SEQ ID NO:2 bearing an MHC Class I or II binding motif, classified in class 514, subclass 44.

16. Claims 70-72 (in part), as specifically drawn to a method of eliciting in a subject an immune response against a cell bearing a polypeptide of SEQ ID NO:1 comprising administering a recombinant polynucleotide encoding an immunogenic polypeptide analog of SEQ ID NO:1 bearing an MHC Class I or II binding motif, classified in class 514, subclass 44.

17. Claim 73 (in part), as specifically drawn to a screening method for determining whether a compound modulates the expression of the mRNA of SEQ ID NO:1 in

a cell comprising contacting the cell with the compound, classified in class 435, subclass 4.

18. Claim 73 (in part), as specifically drawn to a screening method for determining whether a compound modulates the polypeptide of SEQ ID NO:1 in a cell comprising contacting the cell with the compound, classified in class 435, subclass 4.

19. Claim 74, drawn to a screening method for determining whether a compound inhibits the activity of the polypeptide of SEQ ID NO:2 in a cell comprising contacting the cell with the compound and determining whether the exocytosis from the cell or capacitance across the cell membrane is altered, classified in class 435, subclass 4.

20. Claim 75, drawn to a method of detecting a chromosomal translocation of a gene of SEQ ID NO:1 comprising determining whether the pattern of hybridization differs from a normal pattern, classified in class 435, subclass 6.

21. Claim 76, drawn to a method of detecting polymorphic forms of SEQ ID NO:1 comprising comparing the identity of a nucleotide or amino acid at a selected position from the sequence of a test SEQ ID: 1 or 2 gene or polypeptide with

identity of the nucleotide or amino acid at the corresponding position of native SEQ ID NO:1 or 2 , classified in class 435, subclass 6.

The inventions are distinct, each from the other because of the following reasons:

The inventions of Groups 1-2, and 4-21 are materially distinct methods which differ at least in objectives, method steps, reagents and/or dosages and/or schedules used, response variables, and criteria for success. For example, the method steps of Groups 4 and 5 (drawn to diagnosing prostate cancer) differ in the products detected in subjects (polypeptides versus nucleic acids) wherein the criteria for detecting said products would also be distinctly different. Further, Group 6 (drawn to detecting prostate cancer) includes different reagents for employing the method steps which are independent or distinct from the methods of Groups 4 and 5. Groups 7-8 differ, each from the other, in that independent or distinct products are detected (mRNA or polypeptides) which would require different searches and different considerations. Groups 9-13 include five distinct groups because they employ different method steps and different reagents (antisense, inactive analog polypeptides of SEQ ID NO:2 or inactive polypeptides of SEQ ID NO:1, immunotoxins that bind to SEQ ID NO:2 or SEQ ID NO:1), all of which would require different searches and different considerations.

It is noted that the invention of Group 3 and the methods of Groups 4 and 6 are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (I) the process for using the product as claimed can be practiced with another

materially different product or (ii) the product as claimed can be used in a materially different process of using that product [see *MPEP* § **806.05(h)**]. In the instant case the antibody product as claimed can be used in materially different processes such as affinity chromatography, detecting polypeptides, and detecting prostate cancer cells by administering said antibody.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper. Furthermore, because these inventions are distinct for the reasons given above and the search required for one group is not required for another group, restriction for examination purposes as indicated is proper.

Note:

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise **include all the limitations** of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in

accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gary B. Nickol Ph.D. whose telephone number is 571-272-0835. The examiner can normally be reached on M-F, 8:30-5:00 P.M..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler can be reached on 571-272-0871. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Gary B. Nickol Ph.D.
Examiner
Art Unit 1642

GN

Gary B. Nickol